**Practitioner's Docket No. 397037**

## REMARKS

Claims 1-7, 14-21 and 34-52 are pending in the application.

**Claim Rejections – 35 U.S.C. 103(a)**

Claims 1-7, 14-22 and 34-37 stand rejected over EP 0 506,207 (Allen '207). Applicant's attorney requests reconsideration of the rejection, which is stated for the reason given in the Papers of September 26, 2000 and April 26, 2004.

Zinc 8-hydroxyquinoline is particularly claimed. Allen does not teach or suggest the use of 8-hydroxyquinoline. The quinoline-based pharmacologically active agents that are recited on page 4 at lines 4-7 of Allen '207 include only quinoline derivatives. These are specifically 8-hydroxyquinoline sulfate, halogenated quinolines, 7-iodo-8-hydroxyquinoline-5-sulfonic acid, 5-chloro-7-iodo-8-hydroxyquiniline, 5-chlor-8-hydroxyquinoline, 5,7-dicholoro-8hydroxyquinoline, 5,7-dlido-8-hydroxyquinoline, and decamethylene-bis (4-amino-quinaldium chloride)." See page 15 at lines 20-23 (also excluding 8-hydroxyquinioline). These materials do not encompass the specific use of 8-hydroxyquinoline as claimed.

The Declaration of Carl Hansen shows the results of a comparative study in which cancerous lesions were treated with comparable formulations—one containing 8-hydroxyquinoline as claimed and the other containing 8-hydroxyquinoline sulfate. The 8-hydroxyquinoline solution was effective against the lesion, while the 8-hydroxyquinoline sulfate solution was ineffective. This

shows that the use of 8-hydroxyquinoline has achieved a result that differs in kind from the antimycotic use postulated by Allen '207.

Allen '207 merely proposes the use of these quinoline derivatives as antimycotics and never actually used 8-hydroxyquinoline as is presently claimed. The Declaration of Carl Hansen shows that the use of 8-hydroxyquinoline as is claimed provides an anticancer functionality that was: (a) unappreciated by the prior art, and (2) produces a functionality that differs in kind from a representative chemical, 8-hydroxyquinoline sulfate, in the laundry-list of antimycotics suggested by Allen '207. Thus, there is no equivalent substitution of 8-hydroxyquinoline where this difference in functionality is observed.

The rejection is speculative and has been proven incorrect. In essence, the Office shows Allen '207 for a laundry list of antimycotics that may be categorized as a genus of antimycotic quinoline derivatives. The Applicant is claiming use of a species, namely oxyquinoline itself, where the Declaration of Carl Hansen proves that the claimed composition has a different utility—an anticancer utility-- than does the genus.

Lack of known or useful properties weighs heavily against a finding of motivation to make or select a species or subgenus. In *In re Albrecht*, 514 F.2d 1389, 1392, 185 USPQ 585, 587, 590 (CCPA 1975) the prior art chemical so irritated the skin that it was not useful for an anesthetic purpose and, consequently, did not bar the claims at issue. This difference in utility is analogous to the present situation where Allen '207 never reports having actually made or used the disclosed antimycotics of the prior art and the Declaration of

Carl Hansen shows that this antimycotic genus is not equivalently functional with respect to what is claimed.

Discussing the patentability of chemical homologs, *In re Papesch*, 137 USPQ 43, 315 F.2d 381 (CCPA 1963) says:

> The Hass and Henze cases, which are mentioned, antedate section 103 and suggest, by way of dicta, that proof of the existence of unobvious or unexpected beneficial properties in a new compound, which would otherwise appear to be obvious (along with its properties), is indicative of the presence of "invention" and hence of patentability. What this comes down to, in final analysis, is a rather simple proposition: If that which appears, at first blush, to be obvious though new is shown by evidence not to be obvious then the evidence prevails over surmise or unsupported contention and a rejection based on obviousness must fall. Many cases, both before and after the enactment of section 103, have been decided according to such reasoning

The Office confuses the issue by requiring tests to establish this comparative utility difference throughout the entire range that is claimed. This is the effective range for the effect that is desired in the claimed composition. It is an effective but non-escharotic range. The Declaration shows a comparative difference in utility within this range. Since the range is effective for what is claimed and Allen '207 does not refer to any particularly effective portion of this range over another portion of this range, Allen '207 is by this data point within the range shown not to be a bar. The Applicant should not have provide the additional comparative data that is requested because what is shown is sufficient to eliminate Allen '207 as a reference. Even so, additional testing is presently underway to expand the range analysis. The preliminary results are favorable, but the results are as yet incomplete. The Applicant reserves the right to submit

a preliminary amendment with this data once it arrives, if the Office continues to believe this data would be of use.

Therefore, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103.

**Double Patenting**

As the rejection is provisional in nature, Applicants will delay the filing of a terminal disclaimer until it is necessary to do so.

The amended claims are patentable for the above reasons. No additional fees are seen to be due. However, if any additional fees are due, the Commissioner is authorized to charge them to deposit account No. 12-600.

Respectfully submitted,

LATHROP & GAGE

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